

State of North Carolina  
Division of Mental Health, Mental  
Retardation and Substance Abuse Services  
RESEARCH

APSR 65-1  
7/1/87

REPORTING AND APPROVAL OF RESEARCH AGREEMENTS

1. PURPOSE. This regulation describes the procedures for reporting of research, and the procedures for gaining approval for agreements made with outside agencies concerning research in the state institutions.
2. Scope. This regulation applies only to state institutions.
3. References. NONE
4. Definitions
  - A. Sponsored program is a program which is identified by two basic features: it is separately financed in whole or in part by external agencies, or is carried out under the terms of agreements between the institutions and the sponsoring agencies.
  - B. The devices for authorizing sponsored programs are grants, contracts, and cooperative agreements which, although usually associated with specific individuals, are awarded to the Division or the institution.
5. Reporting Ongoing Research Activities. The institutional directors will be responsible for forwarding to the Division Director:
  - A. the minutes of institutional research committee meetings;
  - B. abstracts of research proposals;
  - C. copies of final research reports; and
  - D. an annual report which shall include a list of all research projects which have been started, continued or terminated.

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EFFECTIVE: July 1, 1987  
OPR: Chief of Evaluation and Research  
DISTRIBUTION: B

6. Division Notification and Review of Research Agreements with Outside Agencies.

It is expected that researchers in Division institutions will seek research funds from foundations, federal agencies, or other sources and that agreements are made with universities or other institutions to collaborate on certain aspects of projects. While researchers must be allowed some freedom and discretion for their research, a mechanism must be in place for assuring that the Division is aware of, and has a chance to review, agreements made between an institution and an outside agency providing for the conduct of research or making available the residents of the institutions for research purposes.

A. Procedures

The following procedures shall be followed:

1. All sponsored programs which are carried out by Division institutions or on Division-controlled premises by or under the direction of staff members of Division institutions shall be subject to review and approval by the Division Director or other persons who have been specifically designated by the Division Director. All applications and/or proposals shall be submitted through the Division Director.
2. All formal applications/or proposals shall be submitted to the Division Director at least two weeks before the filing date. In those instances in which it should be assumed that the Director's review will be particularly extensive, preliminary discussions should be initiated by the institution director earlier than indicated above. The application/or proposal shall be accompanied by a statement describing: (a) the proposed research; (b) the means by which the patients rights and interests will be protected; (c) how the research will meet the needs of the Division; and (d) the expected benefits of the research.
3. The Division Director's response to the application/or proposal shall be provided to the institution director within one week of the date of receipt of the application. The Division Director will then transmit the approved application to the funding agency. Applications not approved by the Division Director will be returned to the institution director.

**B. General Criteria**

The general criteria that must be considered in the development of applications for grants, contracts, and cooperative agreements are:

1. Adequate budgetary support, both direct and indirect, is to be provided by the funding agency and other appropriate sources, and no unauthorized obligations are to be assumed by the institution.
2. All sponsored programs and projects must be compatible with the overall procedures and priorities of the Division and of the institution involved.
3. Projects and proposals must be consistent with all pertinent Department and Division policies and regulations.
4. The completed application for support of sponsored programs, with the exceptions noted below, must be forwarded to the Division Director, through the Chief of Research and Evaluation.

**7. Applications Not Requiring Prior Approval of the Division Director**

**A. Guidelines**

The institutional director may locally approve proposed research agreements except for the following:

1. Applications under which the Department, Division, or institution assumes an expressed or implied responsibility to continue the program or activity beyond the life of the grant or to retain personnel initially employed under the grant, contract, or cooperative agreement.
2. Applications involving the creation of a new organizational unit (a department, center, etc.) within the Division or institution.
3. Applications involving the planning or establishment of a new treatment program, or engaging clients in a treatment activity which would put them at greater risk than is normally encountered in their setting.
4. Applications requiring matching funds or contributions that cannot be provided from current institutional resource levels.

**B. Procedures**

Upon a determination by the institution director that prior approval of the Division Director is not required:

1. The application may be forwarded directly to the funding agency by the institution.
2. The transmittal of the application to the funding agency will include the following notation:

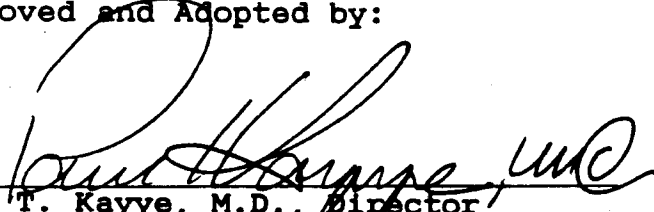
An abstract of this (application or proposal) has been provided to the Director of the Division of Mental Health, Mental Retardation, and Substance Abuse of the Department of Human Resources, State of North Carolina.

3. An abstract of the application shall be forwarded to the Division Director promptly following the transmittal of the application to the funding authority.
4. The Division Director may at any time direct the withdrawal, revision, or amendment of an application or proposal forwarded under the provisions of this section.

**8. Report of Action by Funding Agencies**

Each institution will submit a Report of Awards and Rejections not later than the fifteenth of the month following the month which the activity occurs. The report will include all grant, contract, and cooperative agreement awards and all proposal rejections.

Approved and Adopted by:

  
Paul T. Kaye, M.D., Director  
Division of Mental Health, Mental Retardation  
and Substance Abuse Services